COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 04-VII-2005
C(2005)2567

NOT FOR PUBLICATION

COMMISSION DECISION

of 04-VII-2005

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

ONLY THE GERMAN TEXT IS AUTHENTIC

COMMISSION DECISION

of 04-VII-2005

amending the marketing authorisation for "Apidra - Insulin glulisine", a medicinal product for human use, granted by Decision C(2004)3653

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products,[1],

Having regard to Commission Regulation (EC) No 1085/2003 of 3 June 2003 concerning the examination of variations to the terms of a marketing authorisation for medicinal products for human use and veterinary medicinal products falling within the scope of Council Regulation (EEC) No 2309/93[2], and in particular the first subparagraph of Article 6(10) thereof,

Having regard to the application submitted by Aventis Pharma Deutschland GmbH on 25 March 2005 under Article 6(1) of Commission Regulation (EC) No 1085/2003,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 26 May 2005,

Whereas:

(1) An examination of the major variation type II to the terms of the marketing authorisation for the medicinal product "Apidra - Insulin glulisine", which is entered in the Community Register of Medicinal Products under No(s) EU/1/04/285/001-028 and the placing on the market of which was authorised by Decision C(2004)3653 of 27 September 2004, has shown that the product remains in compliance with the requirements set out in Directive 2001/83/EC of the

[1] OJ L 214, 24.8.1993, p. 1. Regulation as last amended by Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19).
[2] OJ L 159, 27.6.2003, p. 24.

European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) It is therefore appropriate to accept the application in respect of a major variation to the terms of the marketing authorisation and to amend Decision C(2004)3653 accordingly.

(3) For the sake of clarity and transparency, it is advisable, following the amendment of part or parts of the Annexes, to provide for a consolidated version thereof. The Annexes to Decision C (2004)3653 should therefore be replaced,

HAS ADOPTED THIS DECISION:

Article 1

Decision C(2004)3653 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex III is replaced by the text set out in Annex III to this Decision.

Article 2

This Decision is addressed to Aventis Pharma Deutschland GmbH, Brueningstrasse 50, D-65926 Frankfurt am Main, Deutschland.

Done at Brussels, 04-VII-2005

For the Commission
Günter VERHEUGEN
Member of the Commission

[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by [Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34)].